ATTACHMENT D

Pesticide Registration (PR) Notice 2008-2 –
"Guidance for Antimicrobial Pesticide Products With Anthrax-Related Claims."

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 26, 2008

PESTICIDE REGISTRATION (PR) NOTICE 2008-2

NOTICE TO: **Manufacturers, Producers, Formulators and Registrants of Pesticides**

ATTENTION: **Persons Responsible for Federal Registration and Registration of Pesticide Products**

SUBJECT: **Antimicrobial Pesticide Products With Anthrax-Related Claims**

This notice provides guidance to prospective applicants of antimicrobial products that make labeling claims to "inactivate *Bacillus anthracis* (anthrax) spores" (hereafter referred to as "anthrax-related products"). This guidance should help the United States be prepared to respond to incidents involving anthrax spores by assuring that anthrax-related products are registered, that they bear appropriate labeling, and that they are effective when used as directed. In addition, this guidance will help protect public health from the potential risks of anthrax spores by employing terms and conditions of registration that limit the use of anthrax-related products to those who are properly trained and determined to be competent in their use.

In summary, this notice specifies that in order for a product to qualify for a claim of inactivating anthrax spores, an anthrax-related product should be: (a) supported by specific sporicidal efficacy studies that are acceptable to EPA and (b) subject to specific terms and conditions of registration that limit the use of these products to certain persons. Prospective applicants are encouraged to follow the guidance in this notice and consult with EPA prior to applying for registration or amendment of a product when seeking such a claim.

I. Why This Notice is Being Issued

In October 2001, when several letters containing *Bacillus anthracis* (anthrax) spores were introduced into the U.S. Postal Service mail system, no antimicrobial products were specifically registered for inactivating the spores of this particular pathogen. Since that time, EPA's Office of Pesticide Programs (EPA/OPP) has developed guidance on the terms and conditions of registration for the labeling of these products that will limit their use to certain persons, as described below. In addition, the EPA/OPP has developed guidance on laboratory efficacy test methods for demonstrating the effectiveness of antimicrobial products for inactivating anthrax spores on inanimate surfaces. Such efficacy testing guidance will be issued separately from this PR Notice, as described below. It is EPA's intent that registrants will follow the efficacy testing guidance and this PR Notice when applying for registration of anthrax-related products, and that such products, when registered, will be made available to trained and competent civilian and

military personnel who respond to incidents involving anthrax spores.

II. Registration Guidance for Anthrax-related Products

A. Efficacy Test Methods

Currently, no published EPA guidance is available concerning test methods to demonstrate the efficacy of anthrax-related products. However, in July, 2007, EPA/OPP presented its draft efficacy test method guidance to the FIFRA Scientific Advisory Panel (SAP) for review and comment, and the SAP provided comments supportive of EPA's proposal. EPA/OPP expects to issue a draft of Product Performance Test Guidelines for Public Health Uses of Antimicrobial Agents (OPPTS 810.2100 Sterilant—Efficacy Data Recommendations) in 2008 that will recommend efficacy test methods for demonstrating the efficacy of sterilants and sporicides. EPA expects to issue a final version of this efficacy guidance document in 2009. This guidance document will include the efficacy test methods that are recommended for products with anthrax-related claims.

Registrants are encouraged to submit their proposed efficacy test protocols to EPA for review prior to conducting such testing. If an application for registration is received with efficacy data to support a claim to inactivate anthrax spores in the absence of published efficacy test method guidance, EPA will evaluate such data for consistency with the draft guidance that has already been reviewed by the FIFRA SAP.

B. Terms and Conditions of Registration

Due to the high potential risk to human health posed by *B. anthracis* spores (especially spores processed in a manner designed to enhance the potential for inhalation exposure), the Agency intends to establish terms and conditions of registration that limit the use of anthrax-related products to persons who are trained in their use and determined to be competent. These limitations will help assure that the registered antimicrobial products are used safely and effectively. To implement such limitations, the registrant should agree in writing to specific Terms and Conditions of Registration that include items 1-5 below. Once the registrant has agreed to the terms and conditions, and once the Agency has issued a registration, the registrant would need to meet the terms and conditions. The consequences of not meeting the terms and conditions are described in section II.B.5. below. Further, the terms and conditions will be inserted into the Notice of Registration and will apply to all uses on the product's labeling. Accordingly, EPA strongly recommends a separate product registration for the uses that fall within the scope of this PR Notice.

1. Sale and Distribution Limitations

The registrant commits not to sell or distribute the product except to:

- Federal On-Scene Coordinators (FOSC), and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;

- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) in each of the topics described under item 2 below.

The registrant commits to verify, prior to sale or distribution, that the recipient falls within one of the above user categories. For the first two user categories listed above (i.e., FOSCs, U.S. Military personnel, their contractors, and other persons under their supervision), such verification may be accomplished through a critical review of documents, such as a letter on government letterhead, a government purchase order, or a government-issued identification badge.

2. Training and Determination of Competency of Applicators

Where a registrant proposes to sell or distribute anthrax-related products to persons other than FOSCs, trained U.S. Military personnel, and contractors and other response personnel under the supervision of FOSCs or trained U.S. Military personnel, the registrant commits to providing training for such persons and to determining their competency through written examination. The registrant may itself perform the training and competency determination, or enter into a contract with a qualified third party to conduct the training and competency determination on the registrant's behalf. The registrant further commits that the training curriculum will provide for refresher training and competency determination at least every two years and, at a minimum, include instruction concerning:

- Characteristics of and human health hazards posed by *B. anthracis* spores;
- Personal Protective Equipment (PPE) appropriate for protection against *B. anthracis* spores and while using the pesticide product;
- Detailed instructions for safe and effective use of the registered pesticide product and any associated equipment;
- Detailed review of the steps involved in the remediation and restoration process as provided in guidance from federal agencies (e.g., National Response Team Technical Assistance for Anthrax Response, Interim Final Draft, July 2005) as well as review of applicable federal statutory and regulatory requirements and guidance; and
- An assessment of the trained applicator's competency on the above issues through a written examination.

As part of the application for registration, the registrant will develop and submit training materials and a competency examination. EPA intends to review such materials at the same time as it reviews the efficacy data, other data, and labeling submitted with the application for registration. To assist applicants or registrants in developing their written examinations and training materials, EPA intends to pursue the development of a generic competency examination and generic training materials that could be used by any registrant. EPA will likely seek the services of a professional organization/company that has experience in developing competency examinations and training materials to accomplish this task. EPA will also seek the assistance of experts who have experience with remediating sites contaminated with biological materials. Once the exam and training materials are developed to EPA's satisfaction, registrants may add their own product-specific information and submit their examination and training materials in support of registration, as specified in this PR Notice. It should be noted that the Agency may not be able to complete development of the generic competency exam and other training

materials for another year or more. Meanwhile, any registrant who wants to obtain registration of a product bearing anthrax-related claims for sale or distribution to or use by persons whom the registrant must train (e.g., persons other than Federal OSCS, the U.S. Military, and contractors or persons under their supervision as noted above) would have to develop its own training module (including a competency examination and other training materials) and obtain approval of it by the Agency.

3. Records and Reporting

The registrant commits to the following, commencing upon the effective date of registration or, if the anthrax-related claim is added to an existing registration by amendment, upon the effective date of that amendment:

- Maintain accurate, up-to-date records of its required activities under these Terms and Conditions, including:
  --Names of trainers, a listing of their qualifications, and copies of all training materials used.
  --Names and addresses of persons who have been trained and the dates and locations of such training.
  --Names and addresses of persons to whom the pesticide has been sold or distributed as well as the date and location of such sale or distribution and the product and quantity sold or distributed.
- Agree to maintain such records for two years, and to provide copies upon request of any authorized employee of the EPA, or of any State or political subdivision, duly designated by the Administrator.
- Agree that records and reports made or maintained in connection with these Terms and Conditions will not be claimed as confidential business information or trade secrets.

4. Labeling and Sale/Distribution/Use Limitations

The labeling of the affected anthrax-related product will include both a primary label on the container of the product and supplemental labeling that is similar to a technical manual. All primary and supplemental product labeling will be submitted to and reviewed by EPA as part of the application for registration.

- The primary label and the technical manual will bear the following statements on the front panel:

  a. Directly above the product name, within a black outline, and in a font size no smaller than 12 points:

For use only by:

- Federal On-Scene Coordinators and contractors and other trained federal/state/local response personnel under the FOSC's supervision;
- Trained U.S. Military personnel and contractors under their supervision;
- Persons who, within the preceding 24 months, have been trained and determined to be competent by the registrant (or its contractor) following completion of the required training.

Under the terms and conditions of this product's registration, this product may only be sold or distributed by the registrant directly to the persons identified above.

b. Directly under the Directions for Use heading, in a font size no smaller than the heading, a statement that refers to the supplemental labeling, such as: **"See the accompanying technical manual for this product for complete use directions and safety precautions for inactivating *Bacillus anthracis* (anthrax) spores."** The technical manual is supplemental labeling under FIFRA and must comply with all pesticide product labeling requirements and bear the same boxed statement as specified above.

5. Consequence of Non-Compliance with the Terms and Conditions of Registration

The registrant agrees that failure to comply with any terms and conditions of registration specified above, may, at the sole discretion of EPA, result in the issuance of an order canceling the affected registration(s) without a hearing. Before issuing any such order, the Agency will notify the registrant in writing its intention to cancel the registration(s) and specify in such notification the basis for its conclusion that the registrant has failed to comply with the terms and conditions of registration. EPA will allow the registrant ten business days from the receipt of such notification to submit in writing a request to meet with the Director of the Office of Pesticide Programs ("Office Director") before a cancellation order is issued. The Agency will not issue a cancellation order before providing the registrant an opportunity to meet with the Office Director to discuss whether cancellation is appropriate. The registrant agrees that the decision of the Office Director will be final.

III. Implementation

To amend the registration of a currently registered product, the registrant will need to submit: (a) an Application for Registration form (EPA Form 8570-1) marked "Amendment" (for currently registered sterilants/sporicides), (b) appropriate efficacy data in proper format, (c) three copies of the revised labeling with changes clearly circled, (d) a draft competency examination and training materials, and (e) a signed copy of the agreement to the Terms and Conditions of Registration described in section II.B. to be effective in the event the registration is approved.

For new products, the registrant will submit: (a) an Application for Registration form marked "Registration" (EPA Form 8570-1), (b) appropriate efficacy data, (c) three copies of the draft labeling, (d) other forms and data required for a new product, (e) a draft competency examination and training materials, and (f) a signed copy of the agreement to Terms and Conditions of registration described in section II.B. to be effective in the event the amendment is

granted.

Registrants should note that the Terms and Conditions of registration will be inserted into the Notice of Registration and will apply to all uses on the product's labeling. Accordingly, EPA strongly recommends a separate product registration for the uses that fall within the scope of this PR Notice.

All applications for registration are subject to the Pesticide Registration Improvement Act of 2003 with regard to fees charged for applications for registration of pesticide products. Further information can be found at http://www.epa.gov/pesticides/fees/.

Submissions via the U.S. Postal Service: Use the official mailing address below for all submissions directed to the OPP regulatory divisions by mail:

Document Processing Desk (AMEND or REG)
Office of Pesticide Programs (7504PY)
U. S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

PLEASE NOTE: Do not address mail to be sent through the U.S. Postal Service (USPS) to the Arlington, Virginia address below. USPS will return it to you causing delay in processing your actions. There is no U.S. Postal Service delivery at the Virginia address.

Submissions via Personal/Courier Delivery: Deliveries in person or by a commercial courier for the regulatory divisions will be accepted at OPP's Document Processing Desk (7504C). Couriers and delivery personnel must present a valid picture identification card to gain access to the building. Hours of operation for the Document Processing Desk are 8:00 A.M. to 4:30 P.M., Monday through Friday, excluding Federal holidays. Personal and courier deliveries should be directed to:

Document Processing Desk (AMEND or REG)
Office of Pesticide Programs (7504PY)
U. S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

IV. Scope of This Notice

This PR Notice provides general guidance to EPA and to pesticide registrants and applicants, and the public. This guidance is not binding on either EPA or any outside parties, and the EPA may depart from the guidance where circumstances warrant and without prior notice. In their submissions, registrants and applicants may propose alternatives to the recommendations described in this notice, and the Agency will assess them for appropriateness on a case-by-case basis and will respond in writing.

V. Paperwork Reduction Act Notice

The information collection activities associated with the activities described in this PR Notice are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The corresponding Information Collection Request (ICR) document for the training of pesticide applicators has been assigned EPA ICR number 0155.09 and is approved OMB control number 2070-0029. The ICR document for the pesticide application process has been assigned EPA ICR number 0277, and is approved OMB control number 2070-0060. The total estimated respondent paperwork burden associated with the training and certification of a pesticide applicator is an annual average of 3.1 burden hours. The annual average reporting and recordkeeping burden for a registration applicant respondent is estimated to range from 14 hours to 646 hours, depending upon the type of activity. For "Type A" activities, which include new active ingredients and new uses, the estimated annual applicant burden average is 194 hours per application. For "Type B" activities, which include amendments and notifications, the estimated annual applicant burden average is 14 hours per application. The respondent burden estimate for "Type C" reduced risk products is an average of 646 hours per product. A copy of the most recent version of EPA ICR # 0155.09 is available under Docket ID No. EPA-HQ-OPP-2003-0357, and a copy of the most recent version of EPA ICR #0277 is available under Docket ID No. EPA-HQ-OPP-2004-0419. Both dockets may be accessed at www.regulations.gov.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. For the ICR activity contained in this PR Notice, EPA is displaying the applicable OMB control number in the PR Notice above, and the applicable OMB control number also appears on the pesticide application.

VI. For Further Information

If you have questions or need further information about this notice, you may contact Jeff Kempter, Senior Advisor, Antimicrobials Division, 703-305-4448 or kempter.carlton@epa.gov.

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Debra Edwards, Ph.D., Director
Office of Pesticide Programs